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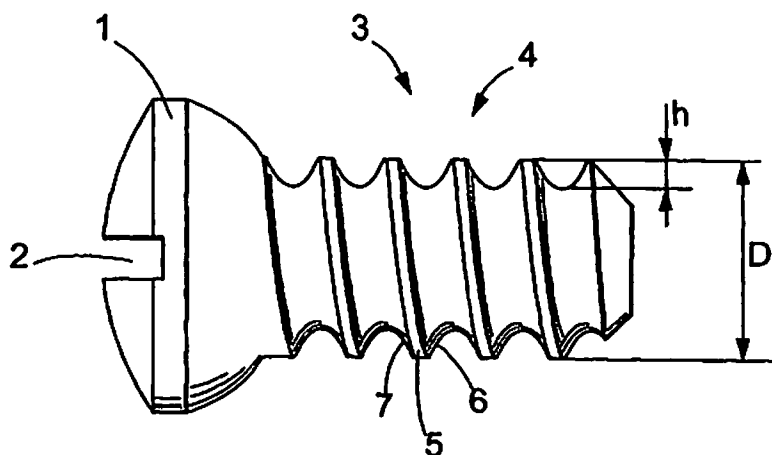
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[Continued on next page]

(54) Title: FASTENING MEANS FOR TREATMENT OF FRACTURES AND MATERIAL FOR PRODUCTION THEREOF



(57) Abstract: A fastening means for treatment of fractures and a material for the production thereof. The fastening means comprises a head (1), which is provided with a contact portion for an installation tool, and an attaching part (3), which comprises a screw thread (4). The fastening means can be fixed into its mounting hole in two ways: like a screw or like a tack. The material for producing a fastening means intended for treatment of fractures is a blend which contains a base material, which is biodegradable polymer and/or copolymer, and one or more copolymer additives so that at room temperature the ductility of the blend is substantially higher than that of pure base material.



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FASTENING MEANS FOR TREATMENT OF FRACTURES AND MATERIAL FOR PRODUCTION THEREOF

5 [0001] The invention relates to a fastening means for treatment of fractures, the fastening means comprising a head, which is provided with a contact portion for an installation tool, and an attaching part, which comprises a screw thread.

10 [0002] The invention further relates to a material for producing a fastening means intended for treatment of fractures, the material being a blend which comprises a base material, which is biodegradable polymer and /or co-polymer.

15 [0003] Screws and tacks which are made of materials that dissolve in the body, i.e. biodegradable materials, and used for treatment of fractures are known. These fastening means are typically used for attaching bars and plates to the bone, which support the bone as the fracture heals. The implant keeps the bone in the right position so that it can heal as well as possible. When the fastening means and the implant are made of materials which dissolve in the body, they do not need to be removed, and thus a removal operation after the bone has healed can be avoided. This is naturally advantageous in respect of patient satisfaction, resources and costs.

20 [0004] Implants are fixed by fitting the fastening means through the holes provided in the implant and by attaching the fastening means to a mounting hole drilled in the bone. Screws are fixed by twisting screw threads into the corresponding threads in the mounting hole. Tacks are fastened by pressing them into the mounting hole, usually by shooting.

25 [0005] In some applications the screw is a better fastening means, in others it is more advantageous to use a tack. The producers of fastening means consequently have a large variety of different screws and tacks available in different sizes. The fact that the shape of a screw differs substantially from that of a tack and they are used differently causes a number of problems.
30 First of all, screws and tacks have to be manufactured on different production lines by different tools. Secondly, the hospital personnel or any other party who performs the operation has to manage a large number of different items of fastening means. Management usually includes several phases, e.g. ordering of items, storage, supply to the actual operation, other handling, etc.
35 Thirdly, a considerable number of instruments, e.g. containers, are needed for different fastening means in the operating space, e.g. in an operating room. All

the above-mentioned issues cause costs and troubles of various kinds: production costs arising from different tools, production lines and the need for space; logistics costs in hospitals; lack of space in the operating room and complexity due to the large number of instruments.

5 **[0006]** The object of the present invention is to provide a new improved fastening means for treatment of fractures and material for the production of said fastening means.

[0007] The fastening means of the invention is characterized in that the attaching part of the fastening means can be fixed in a mounting hole in
10 two different ways: like a screw or a tack.

[0008] The material of the invention is characterized in that in addition to the base material the blend contains a copolymer additive so that at room temperature the ductility of the blend is substantially higher than that of pure base material.

15 **[0009]** The basic idea of the invention is that the fastening means can be fixed in the mounting hole both by twisting the threads of the fastening means into the threads of the mounting hole and by pressing the attaching part of the fastening means into the mounting hole. Furthermore, the idea of a preferred embodiment of the invention is that the head is provided with an attaching part which fastens an installation tool detachably to the fastening
20 means. The basic idea related to the material for producing the fastening means is that the material is a blend which contains a base material and one or more copolymer additives, which comprise one or more monomers, the ductility of the blend being higher at room temperature than that of pure base material. Furthermore, the idea of a preferred embodiment of the material according to the invention is that the copolymer additive contains trimethylene carbonate (TMC) or dioxanone. The basic idea of a second preferred embodiment of the material according to the invention is that the base material contains polylactide, polyglycolide, poly(L-lactide), poly(D-lactide), poly(L-lactide-co-D,L-lactide), poly(L-lactide-co-mesolactide), poly(L-lactide-co-glycolide),
25 poly(L-lactide-co- ϵ -caprolactone), poly(D,L-lactide-co-mesolactide), poly(D,L-lactide-co-glycolide), poly(D,L-lactide-co- ϵ -caprolactone), poly(mesolactide-co-glycolide) and/or poly(mesolactide-co- ϵ -caprolactone). The basic idea of a third embodiment of the material according to the invention is that the share of
30 copolymer additive in the blend is 1 to 50 % by weight, preferably 20 to 50 % by weight and most preferably 20 to 40 % by weight.

[0010] An advantage of the invention is that the fastening means replaces the screw and the tack and thus it can be flexibly applied in various fastening tasks that arise in treatment of fractures. The fastening means simplifies the manufacturing phase because only one kind of fastening means
5 needs to be manufactured. Consequently, the production costs will be lower than previously. The fastening means according to the invention reduces the number of items that need to be managed, which also reduces the costs and simplifies the logistics related to fastening means. The number of instruments needed in the operating room decreases, which simplifies and facilitates the
10 work of the surgeons and other persons participating in the operation. An advantage of the material for producing the fastening means according to the invention is that the material is ductile at room temperature. Thanks to this, the probability that the fastening means breaks when attached by shooting is very low.

15 [0011] The invention will be described in greater detail in the accompanying drawings, in which

Figure 1 is a schematic side view of a fastening means according to the invention,

20 Figure 2 schematically illustrates the fastening means shown in Figure 1 as seen from the head,

Figure 3 is a schematic cross-sectional view of the head of the fastening means shown in Figure 1,

Figure 4 is a schematic cross-sectional view of the threaded section of a fastening means according to a second embodiment of the invention, and

25 Figure 5 schematically illustrates behaviour of materials according to the invention in a tensile strength test.

[0012] Figure 1 is a schematic side view of a fastening means according to the invention. The fastening means comprises a head 1, which is provided with a contact portion for an installation tool. The fastening means
30 further comprises an attaching part 3, which is provided with threads 4. The fastening means can be twisted into a threaded mounting hole in a manner known per se. It should be noted that the threaded mounting hole and its production are known per se to a person skilled in the art, for which reason these will not be described in greater detail in this application. The thread 4 is sub-
35 stantially symmetrical, i.e. the front side 6 and the back side 7 of the ridge 5 of the thread are at the same angle to the ridge 5. Such a thread is rather simple

and economical to produce, as well as the tools needed to make the threaded mounting hole for the thread.

[0013] A special applicator is usually used for fastening a tack. The applicator pushes the tack into a mounting hole with a very quick movement; for this reason the method is called shooting. In shooting the tack, particularly its thread, is subjected to a considerable impact load in the axial direction. The thread 4 of the fastening means according to the invention is low. The height of the thread 4 is preferably at least 5% and at most 20% of the outer diameter D of the thread 4. The thread 4 has to have a certain minimum height to ensure sufficient tightness and fastening. On the other hand, the thread should not exceed a certain minimum height because this would reduce the strength of the thread and/or the stiffness of the fastening means too much. A particularly preferable height h for the thread 4 is 8 to 12% of the outer diameter D of the thread 4. In that case the form factor of the thread 4 profile is very advantageous in respect of its strength. Thus the thread 4 and the fastening means sustain the load caused by shooting into the mounting hole very well. The fastening means of the invention is highly versatile because it can be used both as a screw and as a tack. Versatility simplifies and speeds up the surgeon's work because similar fastening means can be used for all fastening purposes the implant requires.

[0014] The fastening means is preferably made of a blend which contains a base material and one or more copolymer additives, which comprise one or more monomers so that the ductility of the blend at room temperature is higher than that of pure base material. These materials are described in greater detail in connection with Figure 5 and Example 1.

[0015] Figure 2 schematically illustrates the fastening means shown in Figure 1 as seen from the head. The head 1 is provided with a contact portion for the installation tool. In the embodiment shown the contact portion consists of crossing perpendicular grooves 2 at the end of the head 1. An installation tool similar to a crosshead screwdriver, for example, can be fitted into the grooves 2 for twisting the fastening means into the mounting hole. Naturally the installation tools used for pushing the fastening means into the mounting hole like a tack are also fitted into the contact portion. The turnable installation tool can be a manually used screwdriver, a motorized screw twister or a similar wrench known per se. The contact portion can also be some other driver member known per se, e.g. a hex socket, a hex head or the like.

[0016] The head 1 is provided with an attaching part, which in the embodiment of the invention shown in Figures 1 and 2 is a mounting cavity 8 at the intersection of the grooves 2 in the middle of the contact portion. At the end of the installation tool there is a corresponding mounting projection. It should be noted that the installation tools are not shown in the figures because they are known per se. The mounting cavity 8 is dimensioned so that the mounting projection of the installation tool is pressed into the mounting cavity 8, and thus the fastening means fastens detachably to the installation tool. In that case the fastening means stays firmly fastened to the tool regardless of its movements. After the fastening means has been placed in the mounting hole, the fastening tool is detached by pulling and/or twisting the mounting projection from the mounting cavity 8.

[0017] Fastening means of different sizes preferably have a mounting cavity 8 of the same size, and thus they all can be handled using the same installation tool. It should be noted that the attaching part may also differ from what has been described here.

[0018] Figure 3 is a schematic cross-sectional view of the head of the fastening means shown in Figure 1. The mounting cavity 8 of the fastening means is at the spot where the grooves 2 cross. The mounting cavity 8 of the installation tool extends to a distance from the bottom of the grooves 2. The mounting projection of the installation tool fastens firmly to the fastening means because the mounting cavity 8 is deep and the bevelled cutting edges 9 of the mounting cavity and the grooves 2 support the mounting projection over a long distance. The material of the fastening means also yields to some extent as the mounting projection of the installation tool is fitted into it, and the friction of the compressive force caused by the yield locks the fastening means into the tool.

[0019] Figure 4 is a schematic cross-sectional view of a section of the thread of the fastening means according to an embodiment of the invention. The thread 4 is asymmetrical, i.e. the front side 6 of the ridge forms a substantially gentler angle with respect to the ridge 5 than the back side 7. This form reduces friction between the fastening means and the mounting hole when the fastening means is shot into the mounting hole in the direction of arrow P. However, the fastening force of the fastening means is sufficient in the opposite direction.

[0020] Figure 5 schematically illustrates behaviour of materials according to the invention when loaded. The material is a blend, which contains a base material and one or more copolymer additives. The base material is a polymer or a copolymer of lactic acid, L-lactide, D-lactide, D,L-lactide, mesolactide, glycolic acid, glycolide or the like and optionally some other polymer or copolymer of a cyclic ester which is copolymerizable with lactide. The base material can also contain other co-monomers which impart desired properties to the material, such as α , β and γ -hydroxybutyric acid, α , β and γ -hydroxyvaleric acid and other hydroxy fatty acids (C_{11} to C_{25}), such as stearic acid, palmitic acid, oleic acid, lauric acid and the like. Accordingly, the base material can be a polylactide, polyglycolide, poly(L-lactide), poly(D-lactide), poly(L-lactide-co-D,L-lactide), poly(L-lactide-co-mesolactide), poly(L-lactide-co-glycolide), poly(L-lactide-co- ϵ -caprolactone), poly(D,L-lactide-co-mesolactide), poly(D,L-lactide-co-glycolide), poly(D,L-lactide-co- ϵ -caprolactone), poly(mesolactide-co-glycolide), poly(mesolactide-co- ϵ -caprolactone) or the like. The monomer units of the co-polymeric base material can be present in a ratio of 50:50 to 85:15 or in any other suitable ratio in between. For example, suitable co-polymeric base materials include poly(L-lactide-co-D,L-lactide) 70:30, poly(L-lactide-co-D,L-lactide) 80:20, poly(L-lactide-co-glycolide) 85:15 and poly(L-lactide-co-glycolide) 80:20. It should be noted that the polymers and copolymers suitable for use as the base material are known per se and can be easily prepared by preparation methods which are well-known to a person skilled in the art.

[0021] The copolymer additive includes one or more of lactic acid, L-lactide, D-lactide, D,L-lactide, mesolactide, glycolic acid, glycolide or the like and one or more of trimethylene carbonate and dioxanone. Certain advantageous copolymer additives include poly(L-lactide-co-trimethylene carbonate), poly(D,L-lactide-co-trimethylene carbonate), poly(mesolactide-co-trimethylene carbonate), poly(glycolide-co-trimethylene carbonate), poly(L-lactide-co-dioxanone), poly(D,L-lactide-co-dioxanone), poly(mesolactide-co-dioxanone), poly(glycolide-co-dioxanone) and the like.

Example 1

[0022] Adding of copolymer additive to the base material yields a material with ductility better than that of pure base material. This is seen clearly in Figure 5, which illustrates behaviour of five different materials in a

tensile strength test. The ratios of the main components included in the materials shown in Figure 5 are given in Table 1.

Table 1	P(L/LD)LA 70:30 (w-%)	PLLA/TMC 70:30 (w-%)
Material 1	100	0
Material 2	80	20
Material 3	70	30
Material 4	60	40
Material 5	50	50

5

[0023] In Table 1 the abbreviation P(L/LD)LA 70:30 means poly(L-lactide-co-D,L-lactide) 70:30, and PLLA/TMC 70:30 means poly(L-lactide-co-trimethylene carbonate) 70:30. Material 1 is a prior art material into which no copolymer additive has been mixed. Materials 2 to 5 are embodiments of the material according to the invention and thus made of a blend which contains a base material and a copolymer additive, i.e. the base material is poly(L-lactide-co-D,L-lactide) 70:30 and the copolymer additive is poly(L-lactide-co-trimethylene carbonate) 70:30.

[0024] The test results shown in Figure 5 were obtained in tests for which the test pieces were produced as follows: the blends were prepared from generally available components by dry mixing. A desired amount of components were mixed in a Turbula T2F mixer for 30 minutes to obtain a homogenous dry mixture. The dry mixture was dried in vacuum at 60 °C for 6 hours, after which it was melt-blended and injection moulded into test pieces.

[0025] A Fanuc Roboshot Alpha i30A injection moulding machine, in which the diameter of a screw with a standard profile was 16 mm, was used for producing a test piece. During the metering phase the counter pressure was 40 to 60 bar, the screw speed 60 to 100 min⁻¹ and the barrel temperature 160 to 230 °C. In the injection phase the nozzle temperature was 180 to 230°C, the injection speed 80 to 300 mm/s, the maximum injection pressure 2500 bar and the pack pressure 1000 to 2300 bar for 3 to 8 seconds. The mould temperature was 20 to 30 °C and the cooling time 10 to 22 seconds. The cycle time of injection moulding was 20 to 40 seconds.

[0026] The tensile strength test was carried out as follows: a Zwick Z020/TH2A tensile testing machine and a load cell of 10 kN were used. The test was performed at room temperature. Gamma-sterilized test pieces were fixed to the jaws of the tensile testing machine immediately after the sterile
5 package had been opened. Both jaws were provided with three tacks, which were fitted through the corresponding holes provided at both ends of the test piece. The test pieces were loaded at a constant speed of 5 mm/min until they broke.

[0027] As is seen in Figure 5, material 1, i.e. the prior art material,
10 behaves like a hard and brittle material typically does. In other words, its breaking strength is high but it has hardly any ductility. This material cannot be successfully used in the fastening means according to the invention because the probability that the material breaks when the fastening means is shot into a mounting hole like a tack is high. The reason for this is that the fastening
15 means is subjected to a substantially impact load as it quickly penetrates into its mounting hole. Instead, materials 2 to 5, i.e. the materials according to the invention, have a substantially higher ductility than material 1, and thus they sustain the above-mentioned blow-like load substantially better than material 1. Materials 2 to 5 are consequently well suited for use as the material of the
20 fastening means. It is also seen in Figure 5 that the ductility of the material improves and the hardness decreases as the amount of copolymer additive increases. By choosing a suitable base material and copolymer additives and suitable ratios thereof, the hardness and ductility of the material can be adjusted rather freely. Materials 2 and 3 are particularly suitable for use as the
25 raw material of the fastening means of the invention because they are ductile but hard.

[0028] It should be emphasized that substances other than the poly(L-lactide-co-D,L-lactide) 70:30 presented in Example 1 and in Table 2 can be used as the base material and substances other than the poly(L-lactide-co-trimethylene carbonate) can be used as the copolymer additive, as
30 stated above in the application. The following combinations of base material and copolymer can be used in the production of the fastening means, for example:

[0029] - poly(L-lactide-co-D,L-lactide) 80:20 and 20 to 40 % by
35 weight of poly(L-lactide-co-trimethylene carbonate) 70:30,

[0030] - poly(L-lactide-co-glycolide) 85:15 and 20 to 40 % by weight of poly(L-lactide-trimethylene carbonate) 70:30, and

[0031] - poly(L-lactide-co-glycolide) 80:20 and 20 to 40 % by weight of poly(L-lactide-co-trimethylene carbonate) 70:30.

5 [0032] The drawings and the related description are only intended to illustrate the inventive concept. The details of the invention may vary within the scope of the claims. The fastening means can be shaped differently than the embodiments shown in the figures. Fastening means can be produced in different sizes. The material can contain about 50 to 99% of base material, i.e.
10 the total amount of one or more copolymer additives is between 1 and 50% (by weight).

CLAIMS

1. A fastening means for treatment of fractures, the fastening means comprising a head, which is provided with a contact portion for an installation tool, and an attaching part, which comprises a screw thread, wherein
5 the attaching part can be fixed into a mounting hole in two ways: like a screw or like a tack.

2. A fastening means according to claim 1, wherein the screw thread is substantially symmetrical.

3. A fastening means according to claim 1, wherein the screw
10 thread is substantially asymmetrical.

4. A fastening means according to claim 1, wherein the head is provided with an attaching part, which is arranged to fasten the installation tool detachably to the fastening means.

5. A fastening means according to claim 4, wherein attaching part is
15 a mounting cavity provided in the head.

6. A fastening means according to claim 1, wherein the height of the thread is 5 to 20% of the outer diameter of the thread.

7. A fastening means according to claim 6, wherein the height of the thread is 8 to 12% of the outer diameter of the thread.

8. A fastening means according to claim 1, wherein the fastening means is made of a blend which contains a base material and at least one copolymer additive, which comprises one or more monomers, the blend being
20 at room temperature substantially more ductile than pure base material.

9. A fastening means according to claim 8, wherein the copolymer
25 additive contains trimethylene carbonate (TMC) or dioxanone.

10. A fastening means according to claim 9, wherein the copolymer additive contains poly(L-lactide-co-trimethylene carbonate), poly(D,L-lactide-co-trimethylene carbonate), poly(mesolactide-co-trimethylene carbonate), poly(glycolide-co-trimethylene carbonate), poly(L-lactide-co-dioxanone),
30 poly(D,L-lactide-co-dioxanone), poly(mesolactide-co-dioxanone) and/or poly(glycolide-co-dioxanone).

11. A fastening means according to claim 8, wherein the base material contains polylactide, polyglycolide, poly(L-lactide), poly(D-lactide), poly(L-lactide-co-D,L-lactide), poly(L-lactide-co-mesolactide), poly(L-lactide-co-glycolide), poly(L-lactide-co-ε-caprolactone), poly(D,L-lactide-co-mesolactide),
35

poly(D,L-lactide-co-glycolide), poly(D,L-lactide-co-ε-caprolactone),
poly(mesolactide-co-glycolide) and/or poly(mesolactide-co-ε-caprolactone).

12. A fastening means according to claim 11, wherein the base material contains copolymer which is poly(L-lactide-co-D,L-lactide) 70:30, poly(L-lactide-co-D,L-lactide) 80:20, poly(L-lactide-co-glycolide) 85:15 and/or poly(L-lactide-co-glycolide) 80:20.

13. A material for preparing a fastening means intended for treatment of fractures, the material being a blend which contains a base material, which is biodegradable polymer and/or copolymer, wherein in addition to the base material the blend contains one or more copolymer additives so that the ductility of the material mixture is at room temperature substantially higher than that of pure base material.

14. A material according to claim 13, wherein the copolymer additive contains trimethylene carbonate (TMC) or dioxanone.

15. A material according to claim 14, wherein the copolymer additive contains poly(L-lactide-co-trimethylene carbonate), poly(D,L-lactide-co-trimethylene carbonate), poly(mesolactide-co-trimethylene carbonate), poly(glycolide-co-trimethylene carbonate), poly(L-lactide-co-dioxanone), poly(D,L-lactide-co-dioxanone), poly(mesolactide-co-dioxanone) and/or poly(glycolide-co-dioxanone).

16. A material according to claim 13, wherein the share of copolymer additive in the blend is 1 to 50 % by weight.

17. A material according to claim 16, wherein the share of copolymer additive in the blend is 20 to 50 % by weight.

18. A material according to claim 17, wherein the share of copolymer additive in the material mixture is 20 to 40 % by weight.

19. A material according to claim 13, wherein the base material contains polylactide, polyglycolide, poly(L-lactide), poly(D-lactide), poly(L-lactide-co-D,L-lactide), poly(L-lactide-co-mesolactide), poly(L-lactide-co-glycolide), poly(D,L-lactide-co-glycolide), poly(D,L-lactide-co-ε-caprolactone), poly(mesolactide-co-glycolide) and/or poly(mesolactide-co-ε-caprolactone).

20. A material according to claim 13, wherein the base material is a copolymer in which the ratios of monomers range from 50:50 to 85:15.

21. A material according to claim 20, wherein the base material contains poly(L-lactide-co-D,L-lactide) 70:30, poly(L-lactide-co-D,L-lactide) 80:20, poly(L-lactide-co-glycolide) 85:15 and/or poly(L-lactide-co-glycolide) 80:20.

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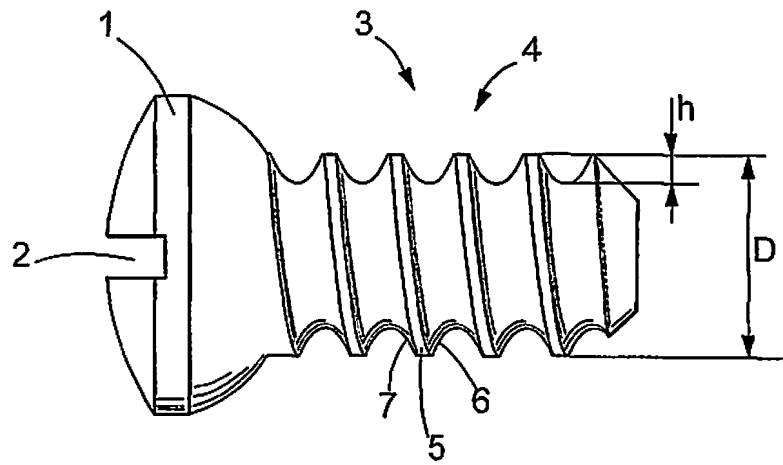


Fig. 1

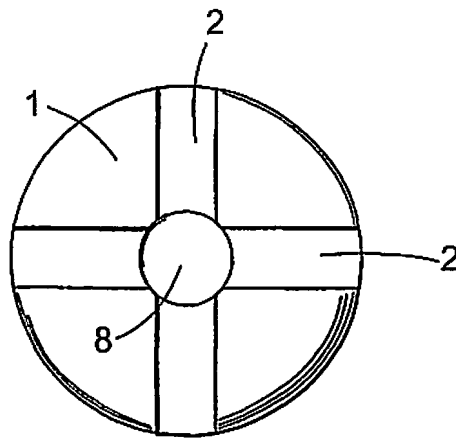


Fig. 2

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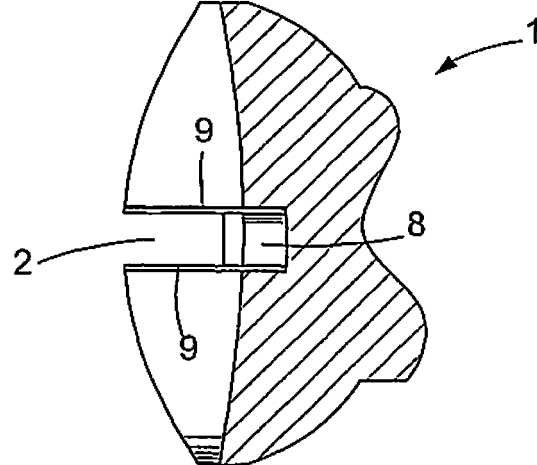


Fig. 3

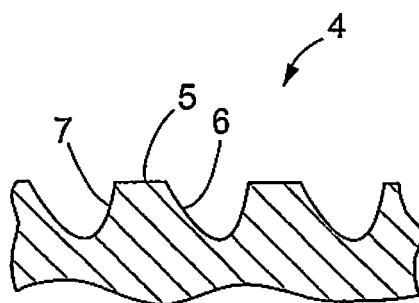


Fig. 4

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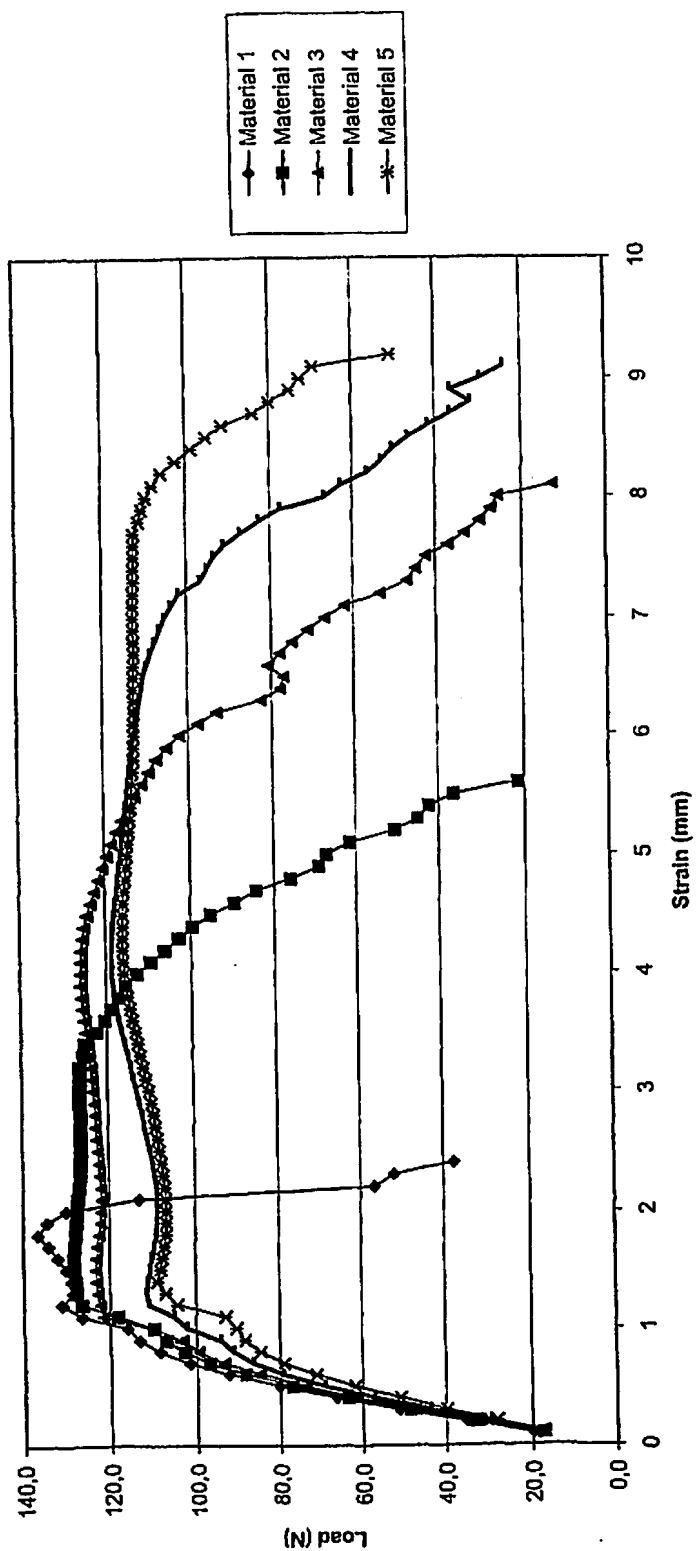


Fig. 5

INTERNATIONAL SEARCH REPORT

International application No.

PCT/FI 02/00424

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 17/86, C08L 64/09, A61L 27/26
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B, C08L, A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	EP 0585476 A1 (UNITED STATES SURGICAL CORPORATION), 9 March 1994 (09.03.94), claim 19, abstract --	1-12
A	US 5658312 A (DAVID T. GREEN ET AL), 19 August 1997 (19.08.97), claim 1, abstract, fig --	1-12
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☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/FI 02/00424

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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